9.4.1 Stent Thrombosis in SPIRIT II and SPIRIT III Pooled Analysis

The results for the pooled analysis rates of stent thrombosis at one year are shown below in Figure 9.4.1-1. Rates were low for both treatments in this pooled analysis and consistent with the published literature[10]. The rates of stent thrombosis were evaluated based on the SPIRIT II and III protocol defined definition and the ARC definition for definite + probable thrombosis (see definitions above in Section 8.2). These data are presented in table 9.4.1-1.

Table 9.4.1-1 Pooled Results for Stent Thrombosis through 1 year (SPIRIT II and SPIRIT III RCT)

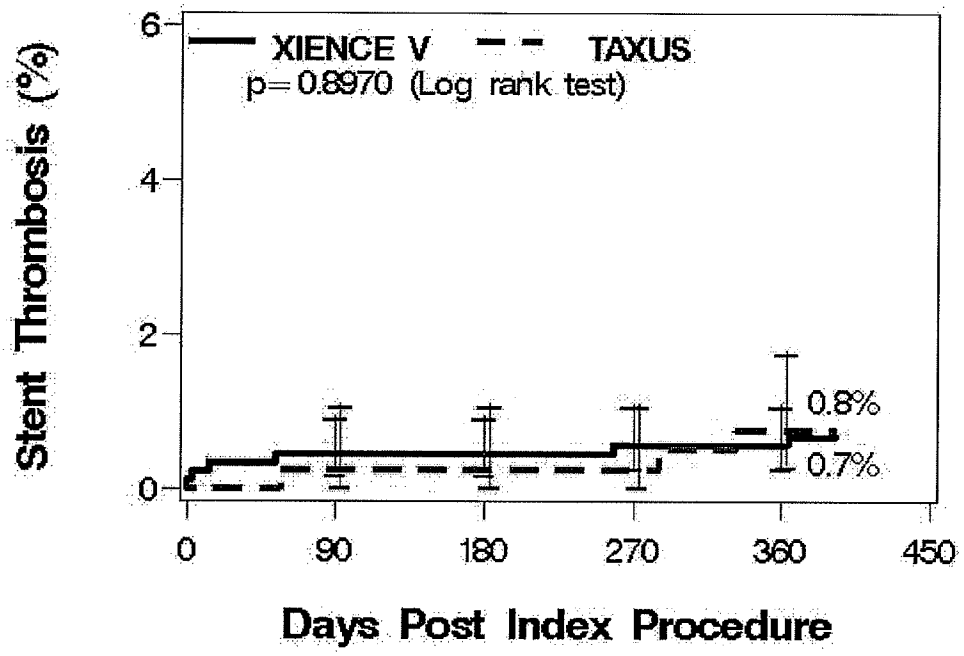
	XIENCE V (N=892)	95% CI[1]	TAXUS (N=410)	95% CI[1]
0 - 30 days				
Protocol	0.3% (3/890)	[0.07%, 0.98%]	0.0% (0/407)	[0.00%, 0.90%]
ARC (definite + probable)	0.4% (4/890)	[0.12%, 1.15%]	0.2% (1/407)	[0.01%, 1.36%]
31 days – 1 year				
Protocol	0.3% (3/866)	[0.07%, 1.01%]	0.8% (3/394)	[0.16%, 2.21%]
ARC (definite + probable)	0.3% (3/867)	[0.07%, 1.01%]	0.8% (3/394)	[0.16%, 2.21%]
0 – 1 year				
Protocol	0.7% (6/867)	[0.25%, 1.50%]	0.8% (3/394)	[0.16%, 2.21%]
ARC (definite + probable)	0.8% (7/868)	[0.32%, 1.65%]	0.8% (3/394)	[0.16%, 2.21%]

Note: timeframe for 1 year includes the follow-up window (365 + 28 days).
[1] By Clopper-Pearson Exact Confidence Interval

[10] Ellis SG CA, Grube E, Popma J, Koglin J, Dawkins KD, Stone GW. Incidence, timing, and correlates of stent thrombosis with the polymeric paclitaxel drug-eluting stent: a TAXUS II, IV, V, and VI meta-analysis of 3,445 patients followed for up to 3 years. *J Am Coll Cardiol.* 2007;49:1043-1051.

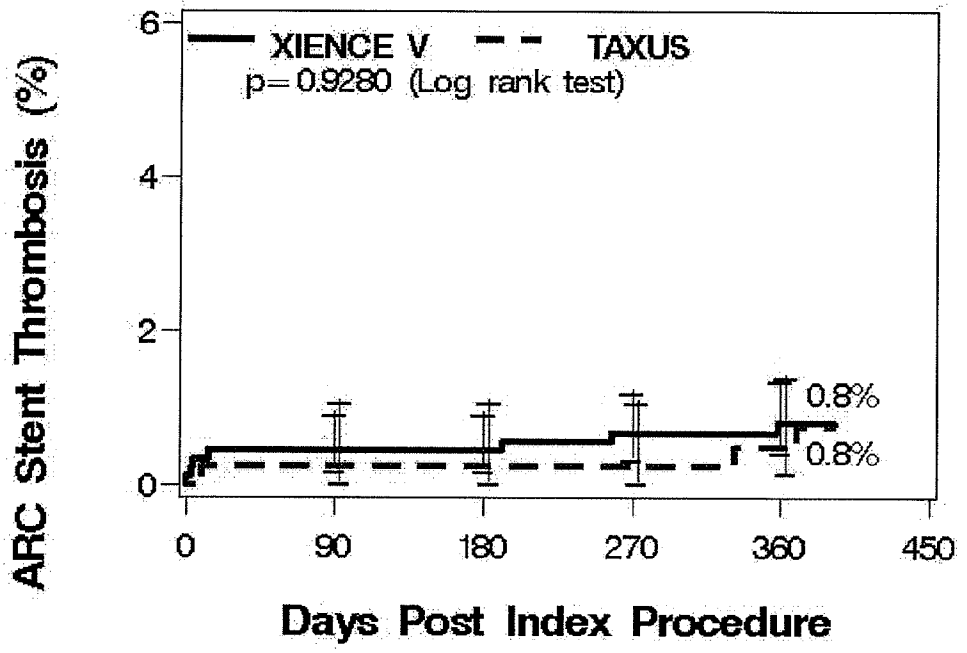
Figure 9.4.1-1: Kaplan Meier Hazard Curves for Time to First Stent Thrombosis Event through 393 Days (Pooled SPIRIT II and SPIRIT III RCTs)

Protocol Defined Stent Thrombosis



Note: P-value is not adjusted for multiplicity and is meant for descriptive purposes only.

ARC Defined Stent Thrombosis (Definite + Probable)



Note: P-value is not adjusted for multiplicity and is meant for descriptive purposes only.

9.4.2 Diabetics in SPIRIT II and SPIRIT III Pooled Analysis

Diabetic subjects comprise an important subject subgroup that is at increased risk for cardiovascular morbidity and mortality. Although diabetic subjects were included in the SPIRIT family of trials, there were no pre-specified hypotheses or trial features that warrant a specific labeled indication for the use of the XIENCE V stent in diabetic individuals.

Table 9.4.2-1 shows the clinical outcomes through 1 year in subjects pooled from SPRIT II and III. The randomization was stratified by history of diabetes to assure a balance between the XIENCE V and TAXUS treatment arms. In XIENCE V patients, there were numerically higher event rates in diabetics compared with non-diabetics. The event rates for TAXUS in diabetics were lower than the event rates for TAXUS non-diabetics. Given the relatively small sample size of the diabetic population and potential for confounding variables, no conclusions can be drawn from these post-hoc analyses.

Table 9.4.2-1: Clinical Results in Diabetics and Non-Diabetics through 1 year (SPIRIT II and SPIRIT III RCT Pooled Population)

	Non-Diabetics XIENCE V (N=643)	Non-Diabetics TAXUS (N=296)	All Diabetics XIENCE V (N=249)	All Diabetics TAXUS (N=110)
TLR	2.5% (16/629)	7.6% (22/290)	4.5% (11/244)	1.0% (1/104)
TVR(CABG/PCI), non TL	2.5% (16/629)	4.1% (12/290)	3.3% (8/244)	2.9% (3/104)
All Death	1.0% (6/631)	2.4% (7/291)	2.0% (5/246)	0.0% (0/104)
Cardiac Death	0.3% (2/631)	1.4% (4/291)	1.2% (3/246)	0.0% (0/104)
Non-Cardiac Death	0.6%(4/631)	1.0%(3/291)	0.8%(2/246)	0.0% (0/104)
MI	1.4% (9/629)	4.5% (13/290)	4.5% (11/244)	2.9% (3/104)
Cardiac Death or MI	1.7% (11/629)	5.2% (15/290)	5.3% (13/244)	2.9% (3/104)
Stent Thrombosis				
Protocol defined	0.5% (3/627)	1.0% (3/287)	1.3% (3/240)	0.0% (0/104)
ARC definite + probable	0.3% (2/627)	0.7% (2/287)	2.1% (5/241)	1.0% (1/104)

Table 9.4.2-2: Clinical Results in Diabetics through 1 year (SPIRIT II and SPIRIT III RCT Pooled Population – XIENCE V Subjects)

	Non-Diabetics (N=643)	All Diabetics (N=249)	Insulin-Dependent Diabetics (N=63)	Non-Insulin-Dependent Diabetics (N=186)
TLR	2.5% (16/629)	4.5% (11/244)	6.5% (4/62)	3.8% (7/182)
TVR(CABG/PCI), non TL	2.5% (16/629)	3.3% (8/244)	1.6% (1/62)	3.8% (7/182)
All Death	1.0% (6/631)	2.0% (5/246)	3.2% (2/63)	1.6% (3/183)
Cardiac Death	0.3% (2/631)	1.2% (3/246)	1.6% (1/63)	1.1% (2/183)
Non-Cardiac Death	0.6% (4/631)	0.8%(2/246)	1.6% (1/63)	0.5% (1/183)
MI	1.4% (9/629)	4.5% (11/244)	9.7% (6/62)	2.7% (5/182)
Cardiac Death or MI	1.7% (11/629)	5.3% (13/244)	9.7% (6/62)	3.8% (7/182)
Stent Thrombosis				
Protocol defined	0.5% (3/627)	1.3% (3/240)	1.6% (1/61)	1.1% (2/179)
ARC definite + probable	0.3% (2/627)	2.1% (5/241)	1.6% (1/61)	2.2% (4/180)

9.4.3 Dual Vessel treatment in SPIRIT II and SPIRIT III Pooled Analysis

Subjects requiring treatment in more than one vessel comprise a subgroup that is at increased risk for cardiovascular events compared with single vessel disease patients. Although subjects requiring both single and dual vessel treatment were included in the SPIRIT family of trials,

there were no pre-specified hypothesis or trial features that warrant a specific labeled indication for the use of the XIENCE V stent in dual vessel individuals.

Table 9.4.3-1 shows the clinical outcomes through 1 year in subjects pooled from SPRIT II and III. The randomization was stratified by the number of vessels treated to assure a balance between the XIENCE V and TAXUS treatment arms. Numerically lower event rates were observed for XIENCE V and TAXUS in single compared to dual vessel treatment. However, given the small sample size for dual vessel treatment, no conclusions can be drawn from this post-hoc analysis.

Table 9.4.3-1: Clinical Results in Single and Dual Vessel Treatment through 1 year (SPIRIT II and SPIRIT III RCT Pooled Population)

	Single Vessel XIENCE V (N=752)	Single Vessel TAXUS (N=344)	Dual Vessel XIENCE V (N=140)	Dual Vessel TAXUS (N=65)
TLR	2.9% (21/735)	4.5% (15/333)	4.3% (6/138)	12.5% (8/64)
TVR(CABG/PCI), non TL	2.3% (17/735)	2.1% (7/333)	5.1% (7/138)	12.5% (8/64)
All Death	1.5% (11/739)	1.2% (4/333)	0.0% (0/138)	4.6% (3/65)
Cardiac Death	0.7% (5/739)	0.6% (2/333)	0.0% (0/138)	3.1% (2/65)
Non-Cardiac Death	0.8% (6/739)	0.6% (2/333)	0.0% (0/138)	1.5% (1/65)
MI	1.9% (14/735)	3.0% (10/333)	4.3% (6/138)	9.4% (6/64)
Cardiac Death or MI	2.4% (18/735)	3.3% (11/333)	4.3% (6/138)	10.9% (7/64)
Stent Thrombosis				
Protocol defined	0.3% (2/729)	0.6% (2/332)	2.9% (4/138)	1.6% (1/62)
ARC definite + probable (TLR not censored)	0.5% (4/730)	0.6% (2/332)	2.2% (3/138)	1.6% (1/62)

10.0 INDIVIDUALIZATION OF TREATMENT

The risks and benefits should be considered for each patient before using the XIENCE V stent. Patient selection factors to be assessed should include a judgment regarding risk of long-term antiplatelet therapy. Stenting is generally avoided in those patients at a heightened risk of bleeding (e.g., patients with recently active gastritis or peptic ulcer disease) in which anticoagulation therapy would be contraindicated.

Antiplatelet drugs should be used in combination with the XIENCE V stent. Physicians should use information from the SPIRIT Clinical trials, coupled with current drug eluting stent (DES) literature and the specific needs of individual patients to determine the specific antiplatelet/anticoagulation regimen to be used for their patients in general practice. See also 5.2 – Precautions, Pre- and Post-Procedure Antiplatelet Regimen, Section 5.6 – Precautions, Use in Special Populations and Section 5.7 – Precautions, Lesion/Vessel Characteristics.

Premorbid conditions that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.

11.0 PATIENT COUNSELING AND PATIENT INFORMATION

Physicians should consider the following in counseling patients about this product:

- Discuss the risks associated with stent placement.
- Discuss the risks associated with an everolimus-eluting stent.
- Discuss the risks of early discontinuation of the antiplatelet therapy.
- Discuss the risks of late stent thrombosis with DES use in higher risk patient subgroups.
- Discuss the risk/benefit issues for this particular patient.
- Discuss alteration to current life-style immediately following the procedure and over the long term.

The following patient materials are available for this product:

- A Patient Information Guide which includes information on coronary artery disease, the implant procedure and the XIENCE V Everolimus Eluting Coronary Stent System (provided to physician, on-line at www.XIENCEV.com/PatientGuide, or by calling customer service 1-800-227-9902).
- A Stent Implant Card that includes both patient information and stent implant information (provided in package)

12.0 HOW SUPPLIED

Sterile: This device is sterilized with ethylene oxide gas, non-pyrogenic. It is intended for single use only. Do not resterilize. Do not use if the package is opened or damaged.

Contents: One (1) XIENCE V Everolimus Eluting Coronary Stent System, one (1) Flushing tool, (for the XIENCE V EECSS Rapid Exchange (RX) Stent System), one (1) Stent Implant Card, one (1) Patient Information Guide.

Storage: Store in a dry, dark, cool place. Protect from light. Do not remove from carton until ready for use. Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

13.0 OPERATOR'S INSTRUCTIONS

13.1 Inspection Prior to Use

- Carefully inspect the sterile package before opening and check for damage to the sterile barrier. Do not use if the integrity of the sterile package has been compromised.
- Do not use after the "Use By" date.
- Tear open the foil pouch and remove the inner pouch. **Note: the outside of the inner pouch is NOT sterile.** Open the inner pouch and pass or drop the product into the sterile field using an aseptic technique.
- Prior to using the XIENCE V Everolimus Eluting Coronary Stent System, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent does not extend beyond the radiopaque balloon markers. Do not

use if any defects are noted. However, **do not manipulate, touch, or handle the stent** with your fingers, which may cause coating damage, contamination or stent dislodgement from the delivery balloon.

Note: At any time during use of the XIENCE V Rapid Exchange (RX) EECSS, if the stainless steel proximal shaft has been bent or kinked, do not continue to use the catheter.

13.2 Materials Required

- Appropriate guiding catheter(s). See Table 1-1, XIENCE V Stent System Product Description
- 2 – 3 syringes (10 – 20 ml)
- 1,000 u/500 ml Heparinized Normal Saline (HepNS)
- 0.014 inch (0.36 mm) x 175 cm (minimum length) guide wire
- Rotating hemostatic valve with appropriate minimum inner diameter [0.096 inch (2.44 mm)]
- 60% contrast diluted 1:1 with heparinized normal saline
- Inflation device
- Pre-deployment dilatation catheter
- Three-way stopcock
- Torque device
- Guide wire introducer
- Appropriate arterial sheath
- Appropriate anticoagulation and antiplatelet drugs

13.3 Preparation

13.3.1 Packaging Removal

Note: The foil pouch is not a sterile barrier. The inner header bag (pouch) within the foil pouch is the sterile barrier. Only the contents of the inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.

1. Carefully remove the delivery system from its protective tubing for preparation of the delivery system. When using a Rapid Exchange (RX) system, do not bend or kink the hypotube during removal.

2. Remove the product mandrel and protective stent sheath by grasping the catheter just proximal to the stent (at the proximal balloon bond site), and with the other hand, grasp the stent protector and gently remove distally. If unusual resistance is felt during product mandrel and stent sheath removal, do not use this product and replace with another. Follow product returns procedure for the unused device.

13.3.2 Guide Wire Lumen Flush

1. Over the Wire (OTW) only: Flush the guide wire lumen with HepNS until fluid exits the distal end of the delivery system.

2. Rapid Exchange (RX) only: Flush the guide wire lumen with HepNS using the flushing tool supplied with the product. Insert the flushing tool into the tip of the catheter and flush until fluid exits the guide wire exit notch.

Note: Avoid manipulation of the stent while flushing the guide wire lumen, as this may disrupt the placement of the stent on the balloon.

13.3.3 Delivery System Preparation

1. Prepare an inflation device/syringe with diluted contrast medium.

2. Attach an inflation device/syringe to the stopcock; attach it to the inflation port of the product. Do not bend the product hypotube when connecting to the inflation device/syringe.

3. With the tip down, orient the delivery system vertically.

4. Open the stopcock to delivery system; pull negative for 30 seconds; release to neutral for contrast fill.

5. Close the stopcock to the delivery system; purge the inflation device/syringe of all air.

6. Repeat steps 3 through 5 until all air is expelled. If bubbles persist, do not use the product.

7. If a syringe was used, attach a prepared inflation device to stopcock.

8. Open the stopcock to the delivery system.

9. Leave on neutral

Note: If air is seen in the shaft, repeat *Delivery System Preparation* steps 3 through 5 to prevent uneven stent expansion.

13.4 Delivery Procedure

1. Prepare the vascular access site according to standard practice.

2. **Pre-dilate the lesion with a PTCA catheter of appropriate length and diameter for the vessel/lesion to be treated.** Limit the longitudinal length of pre-dilatation by the PTCA balloon to avoid creating a region of vessel injury that is outside the boundaries of the XIENCE V Stent.

Note: The labeled stent diameter refers to expanded stent inner diameter.

3. Maintain neutral pressure on the inflation device attached to the delivery system. Open the rotating hemostatic valve as wide as possible.

4. Backload the delivery system onto the proximal portion of the guide wire while maintaining guide wire position across the target lesion.

5. Carefully advance the delivery system into the guiding catheter and over the guide wire to the target lesion. When using a Rapid Exchange (RX) system be sure to keep the hypotube straight. Ensure guiding catheter stability before advancing the stent system into the coronary artery.

Note: If unusual resistance is felt before the stent exits the guiding catheter, do not force passage. Resistance may indicate a problem and the use of excessive force may result in stent damage or dislodgement. Maintain guide wire placement across the lesion and remove the delivery system and guiding catheter as a single unit.

6. Advance the delivery system over the guide wire to the target lesion under direct fluoroscopic visualization. Utilize the radiopaque balloon markers to position the stent across the lesion. Perform angiography to confirm stent position. If the position of the stent is not optimal, it should be carefully repositioned or removed (see Section 5.14 – Precautions, Delivery System Removal). The balloon markers indicate both the stent edges and the balloon shoulders. Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion.

Note: Should **any resistance** be felt **at any time** during either lesion access or removal of the delivery system post-stent implantation, **remove the entire system as a single unit.** See Section 5.14 – Precautions, Delivery System Removal for specific delivery system removal instructions.

7. Tighten the rotating hemostatic valve. The stent is now ready to be deployed.

13.5 Deployment Procedure

CAUTION: Refer to Table 14-1: Typical XIENCE V Stent Compliance for *in vitro* stent inner diameter, nominal pressure, and RBP.

1. Prior to deployment, reconfirm the correct position of the stent relative to the target lesion using the radiopaque balloon markers.

2. Deploy the stent slowly by pressurizing the delivery system in 2 atm increments, every 5 seconds, until stent is completely expanded. Accepted practice generally targets an initial deployment pressure that would achieve a stent inner diameter ratio of about 1.1 times the reference vessel diameter (see Table 14-1). Maintain pressure for 30 seconds. If necessary, the delivery system can be repressurized or further pressurized to assure complete apposition of the stent to the artery wall. **Do not exceed the labeled rated burst pressure (RBP) of 16 atm (1.62 MPa).**

3. Fully cover the entire lesion and balloon treated area (including dissections) with the XIENCE V stent, allowing for adequate stent coverage into healthy tissue proximal and distal to the lesion.

4. Deflate the balloon by pulling negative on the inflation device for 30 seconds. Confirm complete balloon deflation before attempting to move the delivery system. If unusual resistance is felt during stent delivery system withdrawal, pay particular attention to guiding catheter position.

5. Confirm stent position and deployment using standard angiographic techniques. For optimal results, the entire stenosed arterial segment should be covered by the stent. Fluoroscopic visualization during stent expansion should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal coronary artery diameter(s). Optimal expansion requires that the stent be in full contact with the artery wall. Stent wall contact should be verified through routine angiography or intravascular ultrasound (IVUS).

6. If the deployed stent size is still inadequate with respect to reference vessel diameter, a larger balloon may be used to further expand the stent. If the initial angiographic appearance is sub-optimal, the stent may be further expanded using a low profile, high pressure, non-compliant balloon dilatation catheter. If this is required, the stented segment should be carefully recrossed with a prolapsed guide wire to avoid disrupting the stent geometry. Deployed stents should not be left under-dilated.

CAUTION: Do not dilate the stent beyond the following limits.

Nominal Stent Diameter	Dilatation Limit
2.5 mm to 3.0 mm	**3.5 mm**
3.5 mm to 4.0 mm	**4.5 mm**

7. If more than one XIENCE V stent is needed to cover the lesion and balloon

treated area, it is suggested that, to avoid the potential for gap restenosis, the stents be adequately overlapped. To ensure that there are no gaps between stents the balloon marker bands of the second XIENCE V stent should be positioned inside the deployed stent prior to expansion.

8. Reconfirm stent position and angiographic results. Repeat inflations until optimal stent deployment is achieved.

13.6 Removal Procedure

1. Deflate the balloon by pulling negative pressure on the inflation device for 30 seconds. Confirm complete balloon deflation before attempting to move the delivery system. If unusual resistance is felt during stent delivery system withdrawal, pay particular attention to the guiding catheter position.

2. Fully open the rotating hemostatic valve.

3. While maintaining the guide wire position and negative pressure on the inflation device, withdraw the delivery system.

Note: Should **any resistance** be felt **at any time** during either lesion access or removal of the delivery system post-stent implantation, the entire system should be **removed as a single unit.** See Section 5.14 – Precautions, Delivery System Removal for specific delivery system removal instructions.

4. Tighten the rotating hemostatic valve.

5. Repeat angiography to assess the stented area. If post-dilatation is necessary, ensure that the final stent diameter matches the reference vessel diameter. **Assure that the stent is not under-dilated.**

13.7 Post-Deployment Dilatation of Stent Segments

1. All efforts should be taken to assure that the stent is not underdilated. If the deployed stent size is still inadequate with respect to the vessel diameter, or if full contact with the vessel wall is not achieved, a larger balloon may be used to expand the stent further. The stent may be further expanded using a low profile, high pressure, and non-compliant balloon catheter. If this is required, the stented segment should be recrossed carefully with a prolapsed guide wire to avoid dislodging the stent. The balloon should be centered within the stent and should not extend outside of the stented region.

CAUTION: Do not dilate the stent beyond the following limits.

Nominal Stent Diameter	Dilatation Limit
2.5 mm to 3.0 mm	**3.5 mm**
3.5 mm to 4.0 mm	**4.5 mm**

14.0 *IN VITRO* COMPLIANCE INFORMATION

Table 14-1: Typical XIENCE V Stent Compliance
Nominal pressure for each diameter indicated by bold font.

Pressure		Stent ID (mm) by System Size				
(atm)	(MPa)	2.5 mm	2.75 mm	3.0 mm	3.5 mm	4.0 mm
8	0.81	**2.46**	**2.74**	2.90	3.46	3.86
9	0.91	2.52	2.81	**2.97**	**3.55**	**3.95**
10	1.01	2.58	2.87	3.04	3.63	4.03
11	1.11	2.63	2.92	3.10	3.69	4.10
12	1.22	2.68	2.97	3.15	3.75	4.17
13	1.32	2.72	3.01	3.19	3.80	4.23
14	1.42	2.75	3.05	3.23	3.84	4.28
15	1.52	2.78	3.08	3.26	3.89	4.33
16 (RBP)*	1.62	2.81	3.11	3.30	3.93	4.37
17	1.72	2.84	3.14	3.33	3.97	4.42
18	1.82	2.87	3.18	3.36	4.00	4.46

Note: These nominal data are based on *in vitro* testing at 37°C and do not take into account lesion resistance. Ensure full deployment of the stent (see Section 13.5, Operator's Instructions, Deployment Procedure) and confirm the stent sizing angiographically.
*Do not exceed the rated burst pressure (RBP).

15.0 REUSE PRECAUTION STATEMENT

Do not use if sterile barrier is damaged. If damage is found call your Abbott Vascular, Cardiac Therapies representative.

For single patient use only. Do not reuse, reprocess or resterilize.

16.0 PATENTS

This product and/or its use are covered by one or more of the following United States patents: 5,040,548 ; 5,061,273 ; 5,154,725 ; 5,234,002 ; 5,242,396 ; 5,350,395 ; 5,451,233 ; 5,496,346 ; 5,514,154 ; 5,569,295 ; 5,603,721 ; 5,636,641 ; 5,649,952 ; 5,728,158 ; 5,735,893 ; 5,759,192 ; 5,780,807 ; 5,868,706 ; 6,056,776 ; 6,131,266 ; 6,179,810 ; 6,273,911 ; 6,309,412 ; 6,312,459 ; 6,369,355 ; 6,419,693 ; 6,432,133 ; 6,482,166 ; 6,485,511 ; 6,629,991 ; 6,629,994 ; 6,651,478 ; 6,656,220 ; 6,736,843 ; 6,746,423 ; 6,753,071 ; 6,818,247 ; 6,827,734 ; 6,887,219 ; 6,887,510 ; 6,890,318 ; 6,908,479 ; 6,921,411 ; 6,929,657 ; 6,939,373 ; 6,957,152. Other US patents pending. Foreign patents issued and pending.

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Abbott Vascular
Santa Clara, CA 95054-2807 USA

CUSTOMER SERVICE
TEL: (800) 227-9902
FAX: (800) 601-8874
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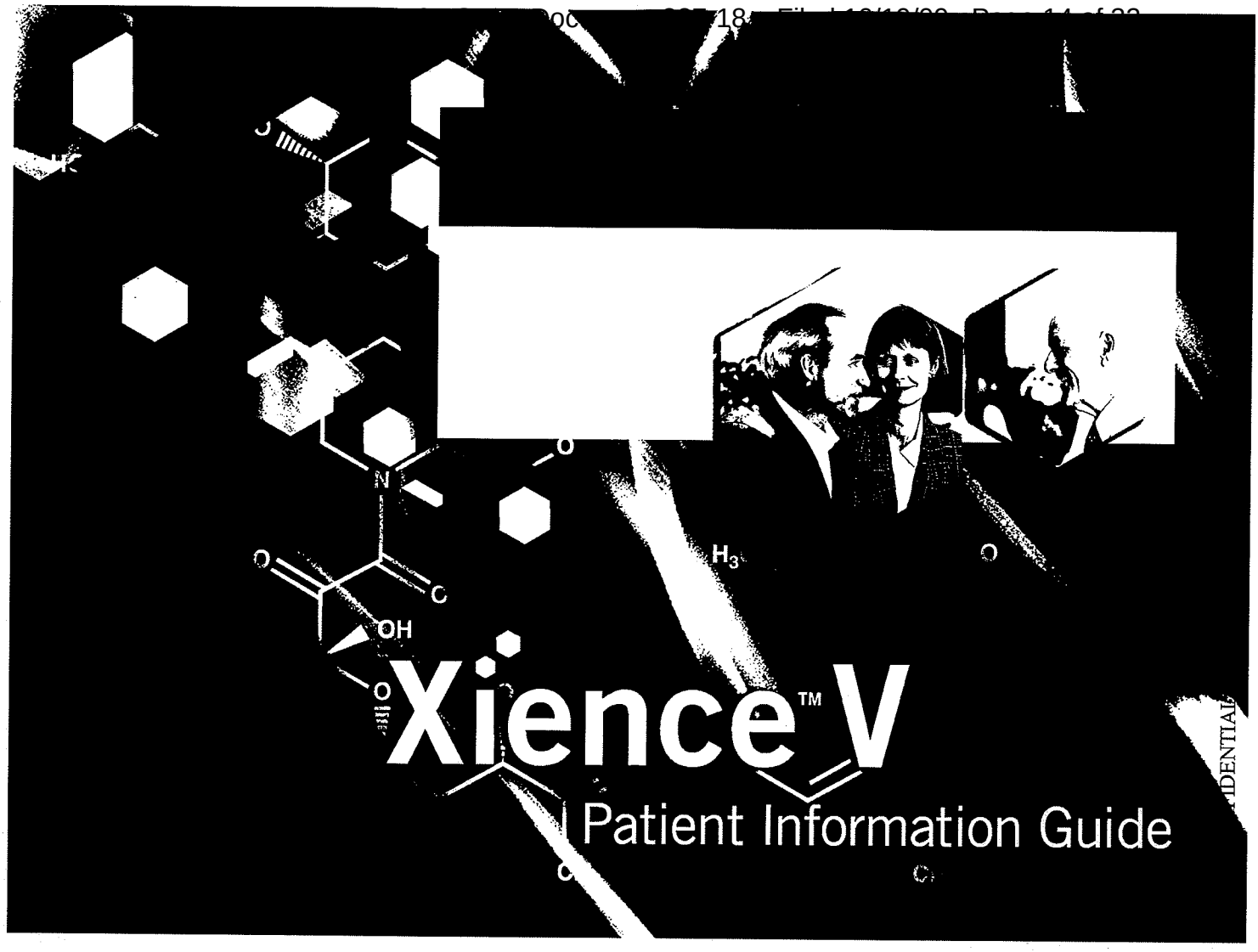
Graphical Symbols for Medical Device Labeling

Manufacturer	REF Catalogue Number	F French Size
Do not reuse, do not resterilize	STERILE EO Sterilized using Ethylene Oxide	Consult Instructions for Use
Use By	LOT Batch Code	Date of Manufacture
Guiding Catheter	PYROGEN Non-Pyrogenic	Contents (Numeral represents quantity of units inside)
Inner Diameter		



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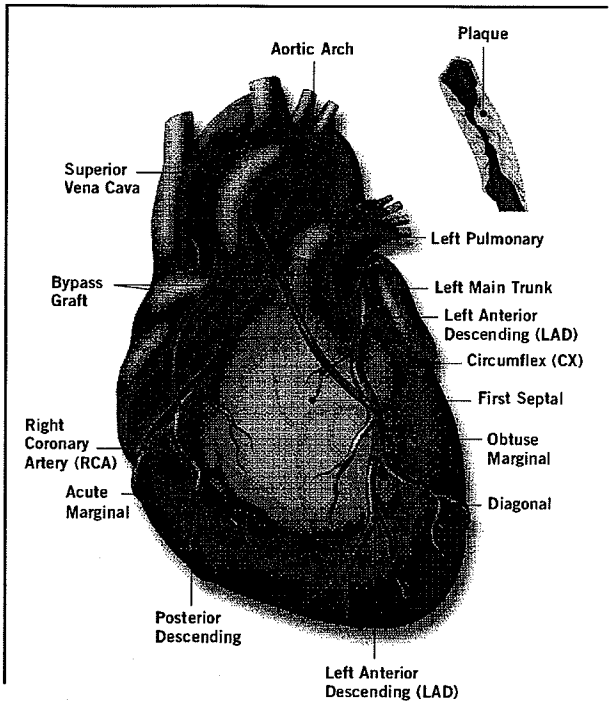
Coronary Artery Disease (CAD)

Causes

Coronary artery disease (CAD) is a condition that occurs when the coronary arteries that supply oxygen-rich blood and nutrients to the heart muscle become narrowed or blocked by a gradual build-up of "plaque". Plaque is made up of cholesterol (fatty deposits), white blood cells, calcium, and other substances that collect under the inner lining of the coronary artery. As the plaque narrows the lumen of a coronary artery, it makes it difficult for adequate quantities of blood to flow to the heart muscle. Over time, the coronary artery becomes less elastic (i.e., it 'hardens') due to plaque deposit. This process is called 'atherosclerosis'. Gradually, blood flow to the heart muscle is reduced, which can cause chest pain (angina). A heart attack is the result of a completely blocked artery, usually by a blood clot forming over a plaque that has broken open (ruptured).

Symptoms of CAD

Gradually, blood flow to the heart muscle is reduced, which can cause chest pain (angina) and shortness of breath. These are often the first signs of coronary artery disease. If the plaque build-up reduces flow only mildly, there may be no noticeable symptoms at rest, but symptoms such as heaviness in the chest may occur with increased activity or stress. Other symptoms that may be experienced are pain in the jaw or radiating to the arms, heartburn, nausea, vomiting and heavy sweating.



When flow is significantly reduced and the heart muscle does not receive enough blood flow to meet its needs, severe symptoms such as chest pain (angina pectoris), heart attack (myocardial infarction), or rhythm disturbances (arrhythmias) may occur.

There are some patients who report no symptoms of CAD and it is possible to have a heart attack without any symptoms of CAD.

CAD is the most common form of heart disease and the number one cause of death of both men and women in the United States. American Heart Association statistics show that women in the United States are three to four times more likely to die from CAD than from breast cancer. Recent research has shown that women experience symptoms different from men. More than one third of women having a heart attack do not report chest pain, heaviness in the chest or chest discomfort. These are the typical symptoms that men report during a heart attack. Women may have symptoms earlier, such as unusual fatigue or sleep disturbances up to one month prior to having a heart attack. These symptoms are very important because in the past these differences have caused women to delay seeking help or treatment. This delay may lead to more severe disease.

Additional warning signs for women are feeling breathless, often without chest pain of any kind, flu-like symptoms, nausea, clamminess or cold sweats, unexplained weakness or dizziness, pain in the upper back, shoulders, neck or jaw and feelings of anxiety. Unfortunately, according to the large, 50-year Framingham Heart Study, over 50% of men and 63% of women who died suddenly of CAD (mostly from heart attack) had no previous symptoms of this disease.

Recent improvements in treatment options, combined with earlier diagnosis, and increased public awareness of the symptoms and risk factors that contribute to this disease are helping to decrease the death rate from coronary artery disease.

Risk Factors of CAD

Two main risk factors for CAD are:

- Increasing age
- Being male or menopausal female[1]

Other risk factors that may increase your chances of developing CAD are:

- Family history of heart disease (close relatives with heart disease at a young age)
- Diabetes
- High blood cholesterol levels
- Smoking
- High blood pressure
- Stress
- Obesity (being overweight)
- High fat diet
- Lack of exercise

1. Menopausal women begin to develop and die of heart disease at a rate equal to men. Menopause is the transition in a woman's life when production of the hormone estrogen in the body falls permanently to very low levels, the ovaries stop producing eggs, and menstrual periods stop.

Diagnosis of CAD

If your doctor suspects that you have CAD or if you have symptoms of the disease, he/she will ask you about your risk factors and your symptoms. A complete physical exam and blood tests to identify injury to your heart muscle will also be completed. In addition, some of the tests used to make the diagnosis are:

Electrocardiogram (ECG/EKG), is a commonly used test that records your heart's electrical activity and can show certain problems such as abnormal heartbeats or damage to the heart muscle. ECG can be done at rest or while you are walking or running on a treadmill or pedaling a stationary bicycle (Stress ECG).

Stress Tests are several types of tests used to evaluate your heart rate and rhythm while you are exercising. The results of these tests help your doctor to determine the areas of heart muscle which are affected by lack of blood flow due to CAD.

Echocardiography, an exam of the heart using sound waves.

Coronary Angiogram or Heart Catheterization, is a procedure carried out in the cardiac catheterization laboratory by a cardiologist. Angiography is a procedure in which coronary arteries are visualized using X-rays. A catheter (long, thin, hollow tube) is inserted into an artery in the groin or arm. The tip of this tube is positioned at the beginning of the arteries supplying blood to the heart and a special fluid called the contrast dye is injected through the tube to visualize the blood vessels on X-rays so that pictures, called angiograms, can be taken. These angiograms allow the doctor to see any blockage and/or narrowings in your coronary arteries and determine their severity.

Using the information gathered from one or more of these tests, your doctor is better able to decide the best treatment plan for you. Your doctor will explain the risks and benefits of your treatment options and answer any questions you or your family may have.

Your Treatment Options

Once a diagnosis has been reached, your doctor will recommend the most appropriate form of treatment depending on the condition and severity of your CAD. CAD can be managed by a combination of changes in lifestyle (eating a healthy, low-saturated fat diet, regular exercise, and quitting smoking) and medical treatment. Medical treatment of CAD may include medications, angioplasty with or without stent placement, or coronary artery bypass graft surgery (CABG or open heart surgery).

Angioplasty

Angioplasty is a procedure used to open blocked arteries. You may also hear it referred to as PTCA (percutaneous transluminal coronary angioplasty). This procedure is performed under local anesthetic in a cardiac catheterization laboratory. A catheter with a small balloon mounted on the end is passed into the coronary artery. The catheter is then positioned at the narrowed portion of the artery and the ballon is inflated. As the balloon inflates, it pushes out against the wall of the coronary artery and compresses the plaque. This opens the narrowing and improves the blood flow to the heart muscle. The balloon is then deflated and the catheter is removed from the artery. In balloon angioplasty, no permanent device remains in the artery after the balloon catheter is removed. A PTCA can be performed with a balloon alone or can involve placement of a permanent device called a stent, within the coronary artery.

Step 1
The doctor guides a catheter with a small balloon through the blood vessel to the narrowed section of the artery. By watching the progress of this catheter on the fluoroscope, the doctor is able to maneuver it into the blocked coronary artery.

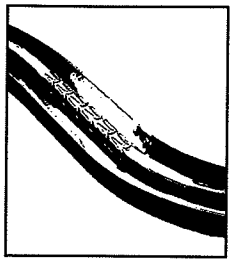
Step 2
When the balloon is inflated, it pushes out against the wall of the artery and compresses the plaque.

Step 3
This makes the inside of the blood vessel larger and improves the blood flow.

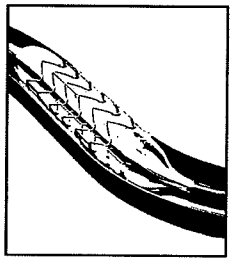
Coronary Artery Stents

Coronary artery stents are devices (small metallic mesh tubes) that are placed over a balloon catheter and delivered to the narrowed portion of the coronary artery. The balloon is used to expand the stent. The stent presses against the narrowed vessel wall holding the narrowing open. This makes a wider channel to improve blood flow to the heart muscle. This may be followed by repeat balloon inflations with the stent delivery system or with a different angioplasty balloon to achieve the result desired by your doctor. Once the balloon has been deflated and withdrawn, the stent stays in place permanently, holding the coronary artery open. The inner lining of the artery grows over the surface of the stent making the stent a permanent part of your artery.

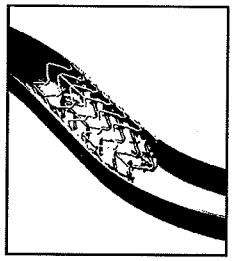
Step 1
The doctor maneuvers the catheter into the blocked artery and inflates the balloon.



Step 2
The stent expands against the vessel wall as the balloon is inflated.



Step 3
Once the balloon has been deflated and withdrawn, the stent stays in place permanently, holding the blood vessel open and improving blood flow.

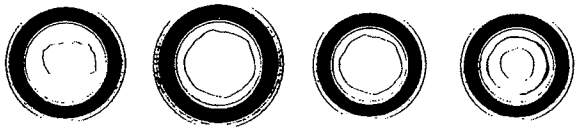


Restenosis

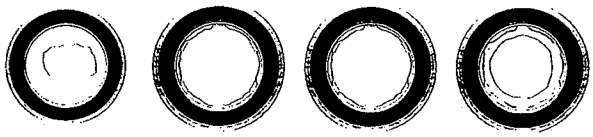
Unfortunately, 30-50% of patients undergoing balloon angioplasty will experience narrowing of the artery within the treated area (restenosis) within the first 6 months. This narrowing can be caused by many factors including vessel recoil and formation of tissue in-growth in the treated area.

Coronary artery angioplasty with stent placement has proven to reduce restenosis compared to balloon angioplasty alone. Still, in about one third of the patients who are treated with coronary angioplasty and stent placement narrowings can reoccur within 6 months of the procedure. This is primarily due to increased tissue in-growth within the stented area.

Restenosis



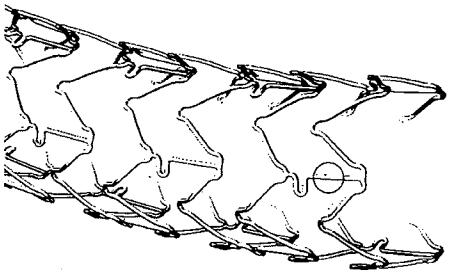
In-stent Restenosis

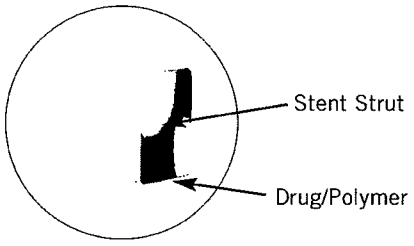


Drug Eluting Stents (DES)

A drug eluting stent is a coronary artery stent that has been coated with a drug and a polymer to deliver the drug locally to the diseased area. The drug is delivered locally to reduce tissue in-growth and therefore the need for re-intervention due to restenosis in the stented area over time (in-stent restenosis).

Your Drug Eluting Stent, the Investigational Device XIENCE™ V Everolimus Eluting Coronary Stent System (XIENCE™ V Stent System)





The XIENCE™ V Stent System is composed of a stent pre-mounted on a delivery system, and a drug eluting coating (including two polymers and the anti-proliferative drug everolimus).

The Stent Platform and Delivery System

The XIENCE™ V Stent is a balloon expandable stent that is made from a single piece of medical grade Cobalt Chromium (CoCr) alloy and is similar in design to the MULTI-LINK VISION® Stent[2] (3.0 mm, 3.5 mm and 4.0 mm) and MULTI-LINK MINI VISION™ Stent[3] (2.25 mm, 2.5 mm). The MULTI-LINK VISION® and MULTI-LINK MINI VISION™ stents are already approved for use as metallic stents and have been used extensively worldwide. These platforms were designed specifically to conform to the natural curves of your arteries, the MULTI-LINK VISION® for larger arteries and MULTI-LINK MINI VISION™ for smaller arteries. The system required to deliver the XIENCE™ V Stent to the narrowed part of the coronary artery is similar to the approved MULTI-LINK VISION® RX Coronary Stent System in design, performance, specifications and materials.

The Drug Eluting Coating

It is comprised of polymer coating and the drug everolimus.

2. The MULTI-LINK VISION® Coronary Stent System received FDA approval on July 16, 2003.
3. The MULTI-LINK MINI VISION™ Coronary Stent System received FDA approval on April 12, 2004.

The Polymer Coating

The XIENCE™ V Stent coating includes two polymers and the drug everolimus. The coating is composed of acrylic and fluoro polymers, both previously approved for use in blood contacting applications. These materials are components of vascular sutures and other drug eluting coronary stents. It is estimated that the drug everolimus contained within the polymer is released into the surrounding tissue and blood over a period of 3 months.

The Drug Everolimus

The drug released by the investigational device XIENCE™ V Stent is everolimus. Everolimus, when given by mouth, has been evaluated in clinical trials in the US and Europe for use in conjunction with other medications to prevent heart and renal transplant rejection. It has also been shown in animal models to prevent cells located in the wall of the coronary artery from growing and narrowing the artery. Everolimus (Certican®)[4] has received market approval in 25 countries of the European Union and Australia. Additionally, everolimus (Certican®) is under review for market approval in the United States. Studies of the XIENCE™ V Stent in animals have shown the potential to reduce the occurrence of re-narrowing of the artery when compared to uncoated metallic stents. Also, a clinical study in Europe (SPIRIT First clinical trial) showed a significant decrease in re-narrowing of treated arteries at 6 months following the stenting procedure in a small number of patients. Thus, everolimus is believed to help reduce the re-narrowing of the stented coronary arteries.

When XIENCE™ V Stent System Should Not be Used (Contraindicated)

- If you have a known hypersensitivity (allergy) or contraindication to everolimus, cobalt, chromium, nickel, tungsten, acrylic and fluoro-polymers and/or cannot be adequately pre-medicated.
- If you cannot take aspirin or blood thinning medications (also called anti-platelet or anti-coagulant therapy).
- If the physician decides that the blockage will not allow complete inflation of the angioplasty balloon or proper placement of the stent.

4. Certican® is the trade name for the drug everolimus and is manufactured by Novartis Pharmaceuticals Corporation.

Know the Risks and Potential Benefits of Treatment with the Investigational Device XIENCE™ V Stent System

Potential adverse events associated with the implantation of a coronary stent in native coronary arteries are:

- Abrupt closure (sudden blockage of the artery)
- Acute myocardial infarction (heart attack)
- Allergic reaction or hypersensitivity to contrast agent
- Aneurysm (a sac-like protrusion from a blood vessel, resulting from a weakening of the vessel wall)
- Arterial perforation (puncture of the coronary artery)
- Arterial rupture (rupture of the coronary artery)
- Arteriovenous fistula (connection between an artery and an adjacent vein)
- Atrial arrhythmias (irregular heart beats in the upper chamber of the heart), including bradycardia (slowing of heart rate) and tachycardia (increased heart rate)
- Bleeding complications, which may require transfusion
- Coronary artery spasm (spasm of the coronary artery causing the artery to narrow)
- Coronary artery or stent embolism (air, fatty deposits, fragments of blood clots, or parts of the stent going downstream and blocking the arteries or the stent)
- Coronary artery or stent thrombosis (fat or fragments of blood clots blocking the arteries or the stent)
- Death
- Distal emboli (air, tissue or thrombotic)
- Drug reactions to anti-platelet agents or contrast medium
- Emergency or non-emergency coronary artery bypass graft surgery
- Fever
- Hypotension (decreased blood pressure) / Hypertension (increased blood pressure)
- Infection and pain at insertion site
- Injury to the coronary artery
- Ischemia, myocardial (decreased blood supply to a part of the heart muscle)
- Myelosuppression (decrease in blood cell production by the bone marrow)
- Nausea (urge to vomit) and vomiting
- Palpitations (feeling of the heart beating rapidly)
- Peripheral ischemia (decrease in blood flow in the blood vessels outside of the heart/nerve injury leading to a decrease in blood flow to the blood vessels outside the heart)
- Pseudoaneurysm (dilatation of an artery with an actual break in one or more layers of its wall)
- Restenosis of stented segment
- Stroke / cerebrovascular accident (CVA)
- Total occlusion (blockage) of coronary artery
- Unstable angina (increase in number, severity and duration of chest pain) or stable angina pectoris (chest pain beginning in the heart)
- Vascular complications, including at entry site, which may require vessel repair

- Ventricular arrhythmias (irregular heart beats in the lower chamber of the heart), including ventricular fibrillation (rapid irregular contraction of the heart muscle) and ventricular tachycardia
- Vessel dissection (tearing)

Potential adverse events related to oral formulation of everolimus (Certican®) taken in the doses of either 1.5 mg/day or 3.0 mg/day for at least 12 months along with other medications (cyclosporin and corticosteroids) in kidney and heart transplant clinical trials include:

- Abdominal (stomach) pain
- Acne
- Anemia (decreased red blood cells)
- Coagulopathy (blood clotting abnormality)
- Diarrhea
- Edema (water retention in the body)
- Hemolysis (destruction of red blood cells)
- Hemolytic Uremic Syndrome (a condition that causes destruction of red blood cells, damage to the lining of the blood vessel walls, and in severe cases, kidney failure)
- Hypercholesterolemia (increased blood cholesterol)
- Hyperlipidemia (increased fat in the blood)
- Hypertension
- Hypertriglyceridemia (increased fat in the blood)
- Hypogonadism in men (decreased functioning of sexual organs)
- Leukopenia (decreased white blood cells)
- Liver function test abnormality, hepatitis (inflammation of the liver), liver disorders
- Lymphocele (abnormal collection of a clear fluid containing white blood cells)
- Myalgia (muscle pain)
- Nausea
- Pain
- Pneumonia (lung infection)
- Pneumonitis (lung inflammation)
- Pyelonephritis (kidney infection)
- Rash
- Renal tubular necrosis (destruction of the kidney tubules)
- Sepsis (generalized infection)
- Surgical wound complication
- Thrombocytopenia (decreased platelet cell count)
- Urinary tract infection
- Venous thromboembolism (blood clot in the vein)
- Viral, bacterial and fungal infections
- Vomiting
- Wound infection

Everolimus when given as an oral medication may interact with substances such as ketoconazole, itraconazole, fluconazole (drugs used for treating fungal infections), ritonavir (drug used to treat HIV infection), erythromycin, clarithromycin, ciprofloxacin, ofloxacin, rifampacin, rifabutin (antibiotics), simavastatin, lovastatin (lipid/fat lowering drugs), digoxin (heart failure drug), calcium channel blockers (blood pressure medication), carbamazepin, phenobarbital, phenytoin (drugs used to treat seizures), sildenafil (Viagra®), terfanadine, astemizole (allergy medications), glucocorticoids (steroid medication), cisapride (drug used to treat heartburn) and grapefruit juice.

The extent of exposure to drug and polymer on the XIENCE™ V Stent is directly related to the number and lengths of the stents implanted. In this study, you can receive one to four XIENCE™ V Stents. If an additional stent is required to cover the narrowing in your coronary arteries for safety measure, additional XIENCE™ V Stents will be used. The use of multiple XIENCE™ V Stents will result in the patients receiving larger amounts of drug and polymer. A kidney transplant patient in clinical trials usually receives one dose by mouth that is about 7 times more than the maximum dose of the drug contained on one XIENCE™ V Stent. Long-term effect of the XIENCE™ V Stent as a permanent device is unknown at this time.

The safety of the XIENCE™ V Stent was shown in the SPIRIT First (60 patients) with patients being followed for 6 months. The incidence of major adverse cardiac events was significantly lower in patients receiving XIENCE™ V Stent (7.7%) than in patients receiving the metallic stent (21.4%) at 6 months following the stenting procedure. The safety and effectiveness of the XIENCE™ V Stent in patients with brachytherapy either before or after stent implantation have not been established. There is no clinical experience on the performance of XIENCE™ V Stent with other types of drug eluting stents. Long term risks and benefits associated with XIENCE™ V Stent are currently unknown.

Your Drug Eluting Stent Procedure

Preparing for Your Procedure

In the days prior to your treatment, make sure you:

- Take all of your prescribed medicines
- Tell your doctor if you are taking any other medication
- Tell your doctor if, for any reason, you cannot take aspirin
- Make sure your doctor knows about any allergies you have
- Refrain from eating and drinking after midnight on the night before your treatment
- Follow all instructions given to you by your doctor or nurse

You may be given a mild sedative to help you relax, but you will not be put to sleep. There are two reasons for this. First, most people find they can cope quite well with any discomfort from the procedure. Secondly, your doctor may need to ask you to take a deep breath while X-rays are being taken to improve the quality of the pictures.

The procedure usually lasts for about 90 minutes, during which time your doctor will ask you to remain very still. For the most part, you will be comfortable but you may feel some pressure or chest pain when the balloon is inflated. This is normal and will quickly fade when the balloon is deflated again.

Your Angioplasty and Stent Placement Procedure

Your procedure will be performed in a cardiac catheterization laboratory (cath lab). This room may be similar to the one where you had your diagnostic angiogram. You will lie on the X-ray table, and an X-ray camera will move over your chest during the procedure. The staff will monitor your heart by attaching several small, sticky patches to your chest and using a specialized ECG recorder and monitor.

The groin is the most common site for catheter introduction and requires a small incision to be made on the inside of your upper thigh. The area will be shaved and cleaned with an antiseptic and you will be given a local anesthetic to numb the area. This incision will allow an introducer sheath (short tube) to be inserted into your femoral artery. Your doctor will then insert a guiding catheter (long, flexible tube) into the introducer sheath and advance it to where the coronary arteries branch off to the heart. A fine guide wire is then advanced through the guiding catheter to the narrowing in the coronary artery. This helps carry all the necessary catheters required during the stenting procedure.

Additional options for catheter introduction are the arm/brachial approach (incision is made on the inside of your elbow) and the transradial approach (incision is made on the inside of your wrist).

After the catheters are inserted, your doctor will inject an X-ray dye through the guiding catheter into your artery to view the narrowing. Your doctor will watch the injection on an X-ray monitor, much like a TV screen. While these X-rays are being taken, your doctor may ask you to take a deep breath and hold it for few seconds. You may also be asked to cough after the X-ray picture is completed to help speed the removal of the X-ray dye from the arteries.

Using the guiding catheter, a balloon catheter is positioned in the narrowing in the coronary artery and the balloon is then inflated. This compresses the plaque and widens the coronary artery. This procedure is called pre-dilatation. The stent mounted on a balloon catheter is delivered to the narrowing in the coronary artery by a delivery catheter. The balloon is then inflated and this expands the stent pressing it against the coronary artery wall. Your doctor may choose to expand the stent further by using another balloon so that the stent can make better contact with the artery wall. This is known as post-dilatation. Once in place, the XIENCE™ V Stent will remain as a permanent implant in your coronary artery.

Making a Swift Recovery

Immediately after the procedure, you'll be returned to a special observation unit, where you heart rhythm, blood pressure and puncture site will be monitored closely.

During the stenting procedure, you will have been given a blood thinning medication (anti-platelet and/or anti-coagulant medication). The effects of the medication will take a few hours to wear off.

Once you are back in the observation room, you may be asked to drink lots of fluids to flush the X-ray dye out of your system as quickly as possible. Due to the puncture site in your groin, you will have to stay in bed for several hours after the procedure, keeping the relevant leg straight and the insertion site immobile.

You may need to stay in the hospital for 1 to 2 days and then you will be discharged into the care of your doctor. Make sure you contact your doctor or the hospital immediately if you experience any discomfort, pain or bleeding once you get home.

Medications

At discharge from the hospital, your doctor may prescribe medications to thin the blood and prevent blood clots from forming on the stent or in your arteries. You will be asked to take a small dose of aspirin throughout the length of this study. In addition, you will be asked to take clopidogrel (Plavix®), or ticlopidine (Ticlid) if you are allergic to Plavix®, for a period of 6 months after your stenting procedure. It is very important for you to follow your medication regimen.

Getting on With Life

To begin with, you will have to return for periodic check-ups. You may be asked to undergo a post-procedure exercise electrocardiogram or angiogram. Regular periodic check-ups will monitor your progress and evaluate your medications, as well as monitor the clinical status of your CAD and how the stent is working for you. Be sure to follow your doctor's instructions carefully and take all your medications according to what is prescribed by your doctor. Keep all follow-up appointments, including laboratory blood tests, follow-up procedures such as angiograms and/or ultrasound if required.

Consider maintaining a healthy lifestyle by regularly exercising, maintaining a healthy diet and avoiding tobacco use. Stent implantation will not limit your activities in any way but you should consult your doctor before you do anything physically demanding. Tell your doctor that you have a coronary stent implant, and keep your stent implant card with you at all times. If anything you have read has raised further questions regarding the procedure, discuss them with your doctor.

The XIENCE™ V Everolimus Eluting Coronary Stent has been shown in non-clinical testing to be MRI safe immediately following implantation. Your stent should not move during an MRI scan. It is unknown if a MRI will heat your stent and possibly change how the drug is released from the stent. Prior to undergoing these examinations, inform your doctor that you have a drug eluting stent.

Definition of Medical Terms

Angina – Chest pain caused by inadequate supply of blood to the heart.

Angioplasty – (also referred to as PTCA) A minimally invasive procedure whereby a balloon dilatation catheter is passed through to the blocked area of an artery. Once inflated the catheter compresses the plaque against the blood vessel wall. An angioplasty can also be performed with a stent.

Anti-coagulant – A medication to prevent or slow the clotting of blood.

Atherosclerosis – A disease that causes narrowing or blockage of arteries caused by a build-up of fat (cholesterol) within the artery wall. The build-up is sometimes referred to as "plaque".

Brachytherapy – The use of a locally delivered dose of radiation to control the process of restenosis.

Cardiac Catheterization Laboratory (Cath Lab) – A sterile X-ray theater in which heart catheterization is performed.

Catheter – A thin, hollow, flexible tube used to access the coronary arteries during an angiogram or during an angioplasty procedure. This catheter can be used to inject medication, fluids or x-ray dye during your procedure. Catheter is also used to describe the device used to deliver the balloon or stent during an angioplasty procedure.

Coronary Angiography (or Heart Catheterization) – A test in which x-ray dye is injected to create images of the coronary arteries and the chamber of the heart. This allows the doctor to see the extent of the disease in the coronary arteries and make a decision on how to best treat the blockages.

Coronary Arteries – The blood vessels that carry oxygenated blood from the aorta to the heart muscle. There are three major coronary arteries: the right coronary artery, the left anterior descending, and the circumflex.

Coronary Artery Bypass Graft Surgery (CABG) – Open-heart surgery to treat CAD

Coronary Artery Disease (CAD) – The formation of blockages or atherosclerotic plaques within coronary arteries that result in restricted blood flow to the heart muscle.

Electrocardiogram (ECG/EKG) – A test that records changes in the electrical activity of the heart. An ECG/EKG may show whether parts of the heart muscle are damaged to due to decreased blood flow to the heart muscle.

In-stent Restenosis – Recurrent blockage or narrowing of a previously stented vessel.

Local Anesthetic – A substance used to numb the area to which it is applied.

Lumen – The inner channel or cavity of a vessel or tube.

Myocardial Infarction (MI) – Also called a heart attack. Permanent damage of an area of the heart tissue, due to interruption in the blood flow to the heart muscle (myocardium).

Percutaneous – Performed through the skin.

Plaque – An accumulation of build-up of fatty deposits, calcium and/or cell debris in an artery that results in narrowing of the lumen.

Restenosis – A recurring blockage caused by excessive cell growth inside the artery or stent, flowing an interventional procedure such as angioplasty.

Stent – A metallic mesh tube that is implanted into an artery during an angioplasty, providing necessary scaffolding to hold the artery open, ensuring blood flow to the heart muscle.

Transluminal – Through the inside opening of a vessel or artery.

Vessel Recoil – When the artery wall is stretched during an angioplasty procedure, the elasticity of the vessel wall may cause the vessel to "shrink" back following the procedure.

Guidant Corporation
3200 Lakeside Drive
Santa Clara, CA 95054
USA
Toll-Free 888.880.2874
International:
Tel 408.845.3400
Fax 408.845.3568
Toll-Free Fax 888.899.2874

Guidant Corporation
Manufacturing Facility
26531 Ynez Road
Temecula, CA 92591
USA
General Inquiries 877.746.4484
Fax 951.914.2531

Guidant Europe NV/SA
Park Lane
Culliganlaan 2B
B-1831 Diegem
Belgium
Tel 32.2.714.14.11
Fax 32.2.714.14.12

Guidant Japan
Shinagawa East One Tower 10F
2-16-1 Konan
Minato-Ku, Tokyo 108-0075
Japan
Tel 81.3.6717.0150
Fax 81.3.6717.0151

For more information, visit our web site at **www.guidant.com**

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